In a letter to HHS Secretary Thompson, Rep. Waxman reveals that FDA enforcement actions against drug manufacturers for false or misleading claims in drug advertisements have dropped by 70% under the Bush Administration.

The Special Investigations Division obtained from FDA copies of over 100 direct-to consumer broadcast advertisements that were broadcast on television in the last year. These advertisements were sent to four independent experts to evaluate for accuracy: Richard Kravitz, M.D., University of California, Davis; Barbara Mintzes, University of British Columbia; Larry Sasich, Pharm. D., Public Citizen Health Research Group; and Michael Wilkes, M.D., Ph.D., University of California, Davis.

These experts found significant problems with many of the ads.

## According to Dr. Wilkes:

"The advertisements I reviewed contained numerous problems (errors, omission or misleading statements/images) and . . . as a group they are often intended to mislead a consumer about the drug¹s effectiveness or the seriousness of their medical condition (creating fear and concern over conditions that are ordinary and have no impact on quality or quantity of life"). . . . I am also bothered by drugs that insinuate or actually claim they are better than other drugs or classes of dugs where there is no data to support such a claim." Similarly, according to Ms. Mintzes:

"[T]he advertisements consistently treat benefit and risk information differently, in ways that tend to minimize even the relatively brief statements of major risks required by the FDA guidance on broadcast advertising. They also fail to provide key information allowing viewers to obtain a realistic sense of how effective a product is or how it compares to other treatment options. . . . I would question whether they are consistent with the aim of regulatory requirements for a fair balance of benefit and risk information in pharmaceutical advertisements and accurate representation of product characteristics." **Documents and Links** 

- Letter to HHS
- Dr. Wilkes's letter to Rep. Waxman
- Ms. Mintzes's letter to Rep. Waxman
- Download Advertisement: Detrol
- Download Advertisement: Ambien
- Download Advertisement: Denavir